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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|----------------|----------------------|-------------------------|------------------|
| 09/975,136 | 10/10/2001 | Dexu Zhu | 524022000100 | 8877 |
| 25225 7 | 590 06/13/2003 | | | |
| MORRISON & FOERSTER LLP | | | EXAMIN | VER |
| SUITE 500 | CENTRE DRIVE | | ZUCKER, PAUL A | |
| SAN DIEGO, CA 92130-2332 | | | ART UNIT | PAPER NUMBER |
| | | | 1621 | |
| | | · | DATE MAILED: 06/13/2003 | 15 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|--|
| Office Action Summary | | 09/975,136 | ZHU ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Paul A. Zucker | 1621 | | | | |
| | The MAILING DATE of this communication ap | pears on the cover sheet with the | correspondence address | | | | |
| Period fo | • • | V 10 077 70 5VD105 4 MONTH | VO) 5004 | | | | |
| THE I - External ferror of the control of the contr | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. It period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be ti ly within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS fron e, cause the application to become ABANDON | imely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status 1)⊠ | Responsive to communication(s) filed on 01 | April 2003 | | | | | |
| 2a)□ | • | his action is non-final. | | | | | |
| ·= | Since this application is in condition for allow | | prosecution as to the merits is | | | | |
| 3)□ Dispositi | closed in accordance with the practice under ion of Claims | | | | | | |
| • | Claim(s) 1-21 is/are pending in the application | n. | | | | | |
| - | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)⊠ | ☑ Claim(s) <u>5-9,11,13-17 and 19-21</u> is/are allowed. | | | | | | |
| 6)⊠ | 6)⊠ Claim(s) <u>1,3 and 4</u> is/are rejected. | | | | | | |
| 7)🖂 | 7)⊠ Claim(s) <u>2,10,12 and 18</u> is/are objected to. | | | | | | |
| , | Claim(s) are subject to restriction and/o | or election requirement. | | | | | |
| · · · | The specification is objected to by the Examine | er. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority ι | ınder 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☒ None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| * 5 | 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) 🗌 🛭 | Acknowledgment is made of a claim for domest | tic priority under 35 U.S.C. § 119 | (e) (to a provisional application). | | | | |
| |) | | | | | | |
| Attachmen | | | | | | | |
| 2) Notic | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal | ry (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |
| S. Patent and T | rademark Office | | | | | | |

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DETAILED ACTION

Current Status

This action is responsive to Applicants' amendment and supplemental declaration of
 April 2003 in Papers No 11 and 12, respectively.

- 2. Receipt and entry of Applicants' amendment is acknowledged.
- 3. Claims 1-21 remain pending.
- 4. The objection to the specification set forth in paragraph 11 of the previous Office Action in Paper No 10 is withdrawn in response to Applicant's amendment.
- 5. The objection to the claims set forth in paragraph 12 of the previous Office Action in Paper No 10 is withdrawn in response to Applicant's amendment.
- 6. The rejections under 35 USC § 112, second paragraph, set forth in paragraph 13 of the previous Office Action in Paper No 10 is withdrawn in response to Applicant's amendment.
- 7. The rejection under 35 USC § 103 set forth in paragraph 14 of the previous Office Action in Paper No 10 is withdrawn in response to Applicants' argument (Page 7, amendment, 3rd full paragraph).

New Rejections and Objections

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sperl et al (Proceedings of the National Academy of Sciences of the United States of America, (4-aminomethyl)Phenylguanidine Derivatives as Nonpeptidic Highly Selective Inhibitors of Human Urokinase 2000, 97(10), pages 5113-5118). Sperl discloses (Page 5114, column 1, Table 1, entry 2) the compound having the following structure:

This corresponds to a compound of the instantly claimed genus of claim 1 in which n= 0; R= C₅ alkyl. Sperl further discloses (Page 5114, column 1, Table 1, entry 2, columns 3-5) enzyme assays of these compounds. These assay solutions of the compound correspond to pharmaceutical compositions of the compound in a pharmaceutically acceptable carrier (water). Claims 1, 3 and 4 are therefore anticipated by Sperl.

Claim Objections

- Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 10. Claim 4 is objected to because of the following informalities: The word "pharmaceutically" on line 1 should be changed to "pharmaceutical". Appropriate correction is required.

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- 11. Claim 10 is objected to because of the following informalities: The word "be" should be added after the word "to" on line 2. Appropriate correction is required.
- 12. Claim 12 is objected to because of the following informalities: The word "a" should be added after the word "is" on line 1. Appropriate correction is required.
- 13. Claim 18 is objected to because of the following informalities: The second word "to" on line 2 should be changed to the word "for". Appropriate correction is required.

Allowable Subject Matter

14. Claims 2, 4, 10, 12 and 18 are drawn to allowable subject matter. Claims 5-9,11 13-17 and 19-21 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The instantly claimed compound (claim 2) and methods for use for the genus of compounds of Formula I is neither disclosed nor fairly suggested by the closest prior art of record: Kamoda et al (US 6,284,791 09-2001), Satoh et al (US 4,732,916 03-1988). Applicants' argument (Page 7, amendment, 3rd full paragraph) that there is no motivation to combine the teachings of Kamoda and Satoh since the compounds of Satoh do not, and are not taught to, have activity against *H. pylori* was found persuasive. One of ordinary skill in the art would not, therefore, have been motivated to combine the teachings of Satoh with those of Kamoda who teaches anti- *H. pylori* agents. The instantly claimed compounds and methods for their use are therefore patentable over the teachings of Kamoda and Satoh.

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Conclusion

15. Claims 1-21 are pending. Claims 1, 3 and 4 are rejected. Claims 2, 10, 12 and 18 are objected to. Claims 5-9,11, 13-17 and 19-21 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker Patent Examiner Technology Center 1600

June 12, 2003

Johann Richter, Ph.D., Esq. Supervisory Patent Examiner

Technology Center 1600